

# Decision Memo for Urine Culture Bacterial (Re-evaluation of Inclusion of Renal Failure in the List of ICD-9-CM Codes Covered) (CAG-00195N)

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## Decision Summary

CMS has determined that ICD-9-CM codes 584.5 (acute renal failure with lesion of tubular necrosis) 584.9 (acute renal failure, unspecified) and 586 (unspecified renal failure) do not flow from the narrative indications in the bacterial urine culture NCD. We intend to modify the NCD for bacterial urine culture to remove these codes from the list of ICD-9-CM codes covered by Medicare for this service.

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## Decision Memo

**This decision memorandum does not constitute a national coverage determination (NCD). It states the intent of the Centers for Medicare & Medicaid Services (CMS) to issue an NCD. Prior to any new or modified policy taking effect, CMS must first issue a manual instruction, program memorandum, CMS ruling or Federal Register Notice giving specific directions to our claims-processing contractors. That issuance, which includes an effective date, is the NCD. If appropriate, the Agency must also change billing and claims processing systems and issue related instructions to allow for payment. The NCD will be published in the Medicare Coverage Issues Manual or Program Memorandum. Policy changes become effective as of the date listed in the transmittal that announces the Coverage Issues Manual revision or Program Memorandum.**

TO: Administrative File: CAG-00195N Urine Culture Bacterial (Re-evaluation of Inclusion of Renal Failure in the List of ICD-9-CM Covered Codes)

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RE: Decision Memorandum for Bacterial Urine Culture

DATE: April 1, 2004

## **I. Decision**

CMS has determined that ICD-9-CM codes 584.5 (acute renal failure with lesion of tubular necrosis) 584.9 (acute renal failure, unspecified) and 586 (unspecified renal failure) do not flow from the narrative indications in the bacterial urine culture NCD. We intend to modify the NCD for bacterial urine culture to remove these codes from the list of ICD-9-CM codes covered by Medicare for this service.

## **II. Background**

On July 7, 2003, CMS began a national coverage determination process for re-evaluation of inclusion of ICD-9-CM codes for renal failure in the list of ICD-9-CM Codes Covered by Medicare for bacterial urine culture. A bacterial urine culture is a laboratory procedure performed on a urine specimen to establish the probable etiology of a presumed urinary tract infection. It is common practice to do a urinalysis prior to a urine culture. The procedure includes growth and isolation of bacteria or other cultivable organisms, and quantification of types present based on morphologic criteria. Isolates deemed significant may be subjected to additional identification and susceptibility procedures as requested by the ordering physician.

The current list of ICD-9-CM Codes Covered by Medicare includes the following ICD-9-CM codes for renal failure:

584.5 Acute renal failure, with lesion of tubular necrosis

584.9 Acute renal failure, unspecified

585 Chronic renal failure

586 Renal failure, unspecified

## **III. History of Medicare Coverage**

In accordance with section 4554 of the Balanced Budget Act of 1997, CMS entered into negotiations with the laboratory community regarding coverage and administrative policies for clinical diagnostic laboratory services. As part of these negotiations, we promulgated a rule that included 23 NCDs. One of these NCDs was for bacterial urine cultures. The rule was proposed in the March 10, 2000 edition of the Federal Register (65 FR 13082) and was made final on November 23, 2001 (66 FR 58788). The final rule called for a 12-month delay in effectuating the NCDs in accordance with the recommendations of the negotiating committee. Thus, the NCDs became effective on November 25, 2002.

In the laboratory NCDs, CMS determined that coverage of specific tests was reasonable and necessary for certain medical indications. These decisions were evidence-based, relying on scientific literature reviewed by the negotiating committee. The NCDs contain a narrative describing the indications for which the test is reasonable and necessary. We also developed a list of ICD-9-CM codes that designate diagnoses/conditions that fit within the narrative description of indications that support the medical necessity of the test. This list is entitled "ICD-9-CM codes covered by Medicare," and includes codes where there is a presumption of medical necessity.

In addition, we developed two other ICD-9-CM code lists. The second list is entitled "ICD-9-CM codes denied," and lists diagnosis codes that are never covered by Medicare. The third list is entitled "ICD-9-CM codes that do not support medical necessity," and includes codes that generally are not considered to support a decision that the test is reasonable and necessary, but for which there are limited exceptions. Tests in this third category may be covered when they are accompanied by additional documentation that supports a determination of reasonable and necessary. We determined in the bacterial urine culture NCD that any ICD-9-CM code not listed in either of the ICD-9-CM covered or not covered sections would be categorized into this group that does not support medical necessity.

#### **IV. Timeline of Recent Activities**

As mentioned above, on March 10, 2000 CMS published a Notice of Proposed Rulemaking (NPRM) in the Federal Register (65 FR 13082). As an addendum to this NPRM, we proposed the 23 NCDs as negotiated by the rulemaking committee for public comment. On November 23, 2001, we published a final rule for coverage and administrative policies for clinical diagnostic laboratory services (66 FR 58788). The bacterial urine culture NCD included the ICD-9-CM codes 584.5, 584.9, 585, and 586 for renal failure, in the list of ICD-9-CM codes covered by Medicare.

In reviewing the bacterial urine culture NCD, we noticed that the narrative indications for bacterial urine culture do not clearly support renal failure as a condition that justifies performing a bacterial urine culture. On July 7, 2003, we announced in a tracking sheet posted on the Medicare coverage Internet site

(<http://cms.hhs.gov/ncdr/trackingsheet.asp?id=100>) that we would be reviewing these codes more carefully with the benefit of public comment to make a determination whether the renal failure codes were appropriately listed in the list of ICD-9-CM Codes Covered by Medicare. At the end of the public comment period, August 6, 2003, we had received one comment. The commenter supported inclusion of codes 584, 585, and 586 in the urine culture NCD. However, they did not show that these codes flowed from the existing narrative indications for urine culture nor did they present scientific evidence to support the inclusion of these codes.

#### **V. FDA Status**

Not Applicable

## **VI.General Methodological Principles**

During the negotiation meetings that led to the development of the 23 clinical diagnostic laboratory NCDs, we stated our intent that the narrative of the NCDs reflect the substance of the determinations. The addition of the coding lists was intended as a convenience to the laboratories and as a means of ensuring consistency among the Medicare claims processing contractors as they interpreted the narrative conditions that support coverage.

We reiterated this position in the November 23, 2001 final rule (66 FR 58795) in responding to public comments requesting the addition of numerous codes to the NCDs. That is, we stated that:

“It is critical that the narrative indications for the proposed policy and the ICD-9-CM codes that support medical necessity be consistent. Thus, in order for us to add codes to the list of ICD-9-CM codes that support medical necessity, those codes must either be determined to be an appropriate translation of an existing indication, or we must add a new indication for the test in the policy narrative.”

Further, in Program Memorandum AB 02-110 we stated our intent as follows:

“The codes included in the NCDs are intended to flow exclusively from the narrative of the NCDs. Therefore, requests for the addition of primary diagnosis codes must include rationale demonstrating the provision of the narrative that supports the inclusion of the code or scientific evidence supporting the inclusion of the condition to the narrative portion of the NCD. Clerical maintenance of the coding lists will be made without following the NCD process. Clerical maintenance may include such actions as revision of codes to be consistent with the annual CPT and ICD-9-CM coding updates, expansion of codes to full range of digits, and correction of code errors that may exist.”

## **VII.CMS Analysis**

As noted above, we have taken the position that the list of ICD-9-CM Codes Covered by Medicare is intended to contain only those codes that flow from the narrative of the indication in the NCD. The following indications are listed in the narrative for bacterial urine culture:

1. A patient's urinalysis is abnormal suggesting urinary tract infections, for example, abnormal microscopic; abnormal biochemical urinalysis, a Gram's stain positive for microorganisms; positive bacteriuria screen by a non-culture technique; or other significant abnormality of a urinalysis.

2. A patient has clinical signs and symptoms indicative of a possible urinary tract infection (UTI). Acute lower UTI may present with urgency, frequency, nocturia, dysuria, discharge or incontinence. Other signs or symptoms may include fever, chills, lethargy, pain in the costovertebral, abdominal, or pelvic areas, prostatitis, urethritis, vaginitis, cervicitis, general debility, acute mental status changes, or declining functional status.

3. The patient is being evaluated for suspected urosepsis, fever of unknown origin or other systemic manifestation of infection but without known source.

4. A test-of cure is generally not indicated in an uncomplicated infection. However, it may be indicated if the patient is being evaluated for response to therapy and there is a complicating co-existing urinary abnormality including structural or functional abnormalities, calculi, foreign bodies, or ureteral/renal stents or there is clinical or laboratory evidence of failure to respond as described in Indications 1 and 2.

5. In surgical procedures involving major manipulations of the genitourinary tract, preoperative examination to detect occult infection may be indicated in selected cases.

6. Urine culture may be indicated to detect occult infection in renal transplant recipients on immunosuppressive therapy.

We do not believe that acute or unspecified renal failure, are included in the above list of indications. While it is possible for severe bacterial urinary tract infection to eventually result in renal failure, urinary tract symptoms, such as those mentioned in indication 2 would give rise to the need for the urine culture rather than renal failure per se.

The only indication above that we find may support the inclusion of renal failure in the list of covered codes is indication number 5 for patients about to undergo renal transplantation. However, renal transplantation would only occur on patients with chronic renal failure, code 585. This indication does not support inclusion of codes 584.5 (acute renal failure, with lesion of tubular necrosis), 584.9 (acute renal failure, unspecified), and 586 (renal failure, unspecified).

Consequently, we intend to issue an NCD to remove ICD-9-CM codes 584.5, (acute renal failure, with lesion of tubular necrosis), 584.9 (acute renal failure, unspecified), and 586 (renal failure, unspecified) from the list of ICD-9-CM codes covered by Medicare. We are retaining code 585 (chronic renal failure) on the list of covered diagnoses. However, we note that this code supports bacterial urine culture only when the patient is about to undergo renal transplantation. All claims with diagnosis code 585 will currently pass the pre-payment edit and are likely to be paid. Contractors may conduct post-payment review of these claims and recover any erroneously paid claims for urine cultures for patients with chronic renal failure that were performed after the effective date of the NCD revision where they find that the patient was not being evaluated for renal transplantation surgery.

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